

BEST AVAILABLE COPY

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
21 April 2005 (21.04.2005)

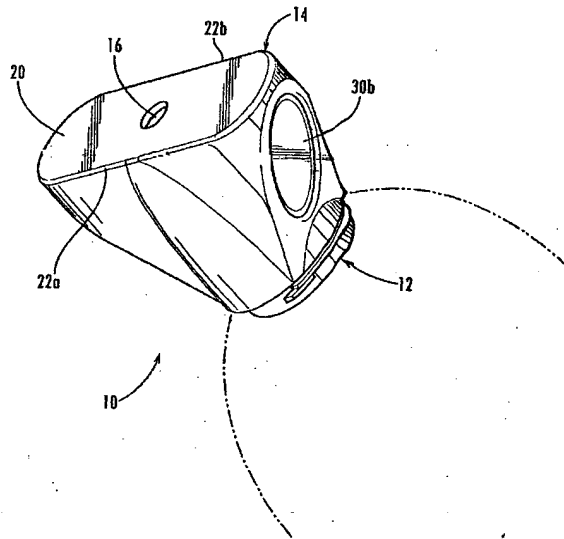
PCT

(10) International Publication Number
WO 2005/034721 A2

- (51) International Patent Classification⁷: A61B
- (21) International Application Number: PCT/US2004/024466
- (22) International Filing Date: 28 July 2004 (28.07.2004)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data: 60/503,805 18 September 2003 (18.09.2003) US
- (71) Applicant (for all designated States except US): FACET TECHNOLOGIES, LLC [US/US]; 1850 Parkway Place, Suite 900, Marietta, GA 30067 (US).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): FLYNN, Stephen [US/US]; 605 Wheatleigh Curve, Peachtree City, GA 30269 (US). LEVAUGHN, Richard, W. [US/US]; 532 Sullivan Road, Newnan, GA 30265 (US). RUF, Christopher, J. [US/US]; 2120 Ithica Drive, Marietta, GA 30067 (US). KENNEDY, Gwenn, E. [US/US]; 5 North Lakeside Drive, Ellenwood, GA 30294 (US). LIPOMA, Michael, V. [US/US]; 4066 Argonne Court, Villa Rica, GA 30180 (US). SALLERAS, Juan, D. [US/US]; 14430 Wyndham Farms Drive, Alpharetta, GA 30004 (US). HOLZAPFEL, Jac [US/US]; 106 Fen Way, Peachtree City, GA 30269 (US). RAMOS, Sylvia [US/US]; 1850 Parkway Place, Suite 900, Marietta, GA 30067 (US).
- (74) Agent: GROFF, Bradley, K.; Gardner Groff, P.C., Paper Mill Village, Building 23, 600 Village Trace, Suite 300, Marietta, GA 30067 (US).
- (81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.
- (84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH,

[Continued on next page]

(54) Title: LANCING DEVICE END CAP WITH BLOOD-DIRECTING CONTACT FACE



(57) Abstract: An endcap for a lancing device. The endcap has a substantially planar contact face surrounding an opening for passing a lancet tip. The contact face has a length substantially greater than its width, and at least one side edge along its length. The user tips the lancing device to bring a side edge into contact with the skin several inches from the intended sampling site, draws the contact face along the skin toward the sampling site, and lances the skin to obtain a fluid sample. The contact face can be repeatedly drawn along the skin toward the sampling site to stimulate blood-flow until the desired sample size is obtained.

WO 2005/034721 A2



GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *without international search report and to be republished upon receipt of that report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

LANCING DEVICE END CAP WITH BLOOD-DIRECTING CONTACT FACE

Cross-Reference to Related Application

[0001] This application claims the benefit of U.S. Provisional Patent Application Serial No. 60/503,805, filed September 18, 2003, the entirety of which is hereby incorporated herein by reference for all purposes.

Technical Field

[0002] The present invention relates generally to medical devices and procedures, ~~and more particularly to lancing devices for sampling blood or other bodily fluids.~~ The invention more particularly relates to an end cap for use in conjunction with a lancing device that allows for the collection of an increased volume of blood or bodily fluid to be sampled.

Background of the Invention

[0003] Many medical procedures require puncturing of the skin, and sometimes underlying tissues, of a human or animal subject. For example, a sharp lancet tip is commonly used to puncture the subject's skin for sampling of blood or other body fluid, as for example in blood glucose monitoring by diabetics. Generally, lancet blades or needles are much thinner than traditional hypodermic syringe needles, and therefore result in less pain to the patient. A lancet having a sharp lancing tip typically is mounted, permanently or releasably, to the drive mechanism of a lancing device. The drive mechanism includes one or more springs, cams, motors, or other mechanism(s) for moving the lancing tip from a retracted position shielded within a housing of the lancing device to an extended position outside of the housing for lancing the subject's skin. The lancing device may also include a cocking mechanism for arming the drive mechanism, and/or a triggering mechanism for firing the device. The housing of the lancing device typically includes an endcap with an opening through which the lancing tip extends in its extended position. The endcap may

be releasably or permanently attached to the remainder of the housing, or can comprise an integral part of the housing.

[0004] One common problem that has been found to exist with many known lancets and lancing devices is the closure of the puncture site before an adequate volume of blood has been collected. Premature closure of the puncture requires additional blood to be drawn from the patient, often in a separate and sometimes less desirable location, resulting in an increase in pain and stress to the subject. Costs also increase, as multiple lancets are required to acquire an adequate sample. This is particularly the case when alternate lancing sites other than the fingertips, such as for example the forearm or earlobe, are lanced. Lancing at such alternate lancing sites may be desirable because repeated lancing of the fingertips can result in callous formation, leading to less consistent sampling and decreased sensitivity of the fingertips. In addition, the fingertips have a greater density of nerve endings than alternate lancing sites, resulting in greater pain sensation from fingertip lancing than lancing at alternate sites. To increase patient compliance with a prescribed sampling regimen, it is desirable to minimize pain resulting from the lancing operation. However, because alternate sites typically contain a lower density of capillaries or a deeper capillary bed than the fingertips, alternate lancing sites often yield insufficient sample sizes or are prone to premature closure.

[0005] Attempts have been made to provide lancing devices that inhibit premature closure of the puncture site and yield increased sample size. Such attempts have included the use of a stimulator member slidably mounted to the housing for cyclically pumping around the puncture site to "milk" the wound. Although utilizing the aforementioned pumping sequence may allow a larger sample to be collected before closure of the puncture site, occasionally a sample is still insufficient, and another lancing operation to collect blood or analytic fluid is required. Additionally, the repeated application and release of pressure from such pumping can result in contact between the sample and the lancing device, smearing and/or contaminating the sample and necessitating another lancing

operation, and/or can lead to bruising of the tissue surrounding the lancing site. Also, the provision of a translationally mounted stimulator member results in increased complexity and cost of the lancing device.

[0006] Thus it can be seen that needs exist for improved lancing devices and methods to facilitate increased sample volume of blood or other analytic fluid, and to prevent premature closure of the sampling site. Needs further exist for such mechanisms and methods that are readily adaptable to current lancing devices and procedures, and which can be utilized for lancing at fingertip as well as alternate sample collection sites.

Summary of the Invention

[0007] In example forms, the present invention is an endcap for a lancing device that enables collection of an increased volume of blood or other body fluid to be sampled from a lancing site of a human or animal subject. The device of the present invention is suitable for use at fingertip lancing sites, but is also well suited for use at alternate lancing sites such as the forearm and/or earlobe. In further embodiments, the invention is a sampling method for increasing collected sample size of blood or other body fluid from a lancing site.

[0008] In one aspect, the present invention is an endcap for a lancing device. The endcap preferably has a first end for connection to the lancing device and a second end comprising a contact face surrounding an opening for passing at least the sharp tip portion of a lancet. The contact face preferably has a length substantially greater than its width, and has at least one side edge along its length.

[0009] In another aspect, the invention is an endcap for a lancing device. The endcap preferably has a first end for connection to the lancing device and a second end comprising a substantially planar contact face surrounding an opening for passing at least the sharp tip portion of a lancet. The contact face preferably has a length substantially greater than its width and has at least one straight side edge along its length. The endcap preferably also has outwardly flared first and second sides between its first and second ends, each outwardly flared side having a gripping surface thereon.

[00010] In still another aspect, the invention is a lancing device for collecting a sample of body fluid from a sampling site on the skin of a subject. The lancing device preferably includes a lancet and a housing comprising an endcap, the lancet being movable between a first position within the housing and a second position wherein at least a sharp tip portion of the lancet extends through an opening in the endcap. The endcap preferably has a substantially planar contact face surrounding the opening, the contact face having a length substantially greater than its width and having at least one straight side edge along its length.

[00011] In another aspect, the invention is a method of lancing skin to collect a fluid sample, the method including the steps of placing a contact face of a lancing device against a subject's skin a distance away from a lancing site, drawing the contact face along the skin toward the lancing site, and lancing the skin at the lancing site

[00012] These and other aspects, features and advantages of the invention will be understood with reference to the drawing figures and detailed description herein, and will be realized by means of the various elements and combinations particularly pointed out in the appended claims. It is to be understood that both the foregoing general description and the following brief description of the drawings and detailed description of the invention are exemplary and explanatory of preferred embodiments of the invention, and are not restrictive of the invention, as claimed.

Brief Description of the Drawing

[00013] **FIGURE 1** shows a perspective view of an endcap for a lancing device according to an example embodiment of the present invention.

Detailed Description of Example Embodiments

[00014] The present invention may be understood more readily by reference to the following detailed description of the invention taken in connection with the accompanying drawing figures, which form a part of this disclosure. It is to be understood that this

invention is not limited to the specific devices, methods, conditions or parameters described and/or shown herein, and that the terminology used herein is for the purpose of describing particular embodiments by way of example only and is not intended to be limiting of the claimed invention. Also, as used in the specification including the appended claims, the singular forms "a," "an," and "the" include the plural, and reference to a particular numerical value includes at least that particular value, unless the context clearly dictates otherwise. Ranges may be expressed herein as from "about" or "approximately" one particular value and/or to "about" or "approximately" another particular value. When such a range is expressed, another embodiment includes from the one particular value and/or to the other particular value. Similarly, when values are expressed as approximations, by use of the antecedent "about," it will be understood that the particular value forms another embodiment.

[00015] With reference now to the drawing figure, Figure 1 shows an example embodiment of an endcap 10 for a lancing device according to the present invention. The endcap 10 preferably comprises a first end 12 for releasable or permanent attachment to the housing of a lancing device. Alternatively, the endcap forms an integral part of the housing of the lancing device. The endcap 10 can be adapted for use with any of a variety of standard, commercially-available or later-developed lancing devices, by appropriate configuration of coupling or attachment features of the first end 12. The second end 14 of the endcap 10 preferably defines the opening 16 through which the sharp lancet tip projects in its extended position to penetrate the skin at the intended lancing site. The endcap is preferably formed of an engineering or medical-grade polymer, plastic, or other material.

[00016] The endcap 10 preferably comprises a substantially planar contact face 20 surrounding the opening 16. The contact face 20 preferably comprises a length substantially greater than its width, and defines at least one side edge, and preferably first and second side edges 22a, 22b, along its length. In example embodiments, the length of the first and second side edges 22a, 22b is at least about three-quarters of an inch (3/4"),

and more preferably at least about one inch (1"). The ends of the contact face along its width are preferably smoothly curved or radiused, or are obliquely angled away from the side edges 22a, 22b. The sides of the endcap 10 between the first and second ends 12, 14 preferably flare outwardly toward the second end 14, and define one or more recesses or gripping surfaces 30.

[00017] In a preferred method of operation according to the present invention, the user grips the lancing device, preferably with his or her thumb and forefinger engaging the gripping surfaces 30a, 30b. The lancing device is placed with the contact face 20 against the skin a distance (preferably about one to three inches) away from the intended lancing site. A steady downward pressure is applied against the skin, and the contact face is drawn across the skin toward the lancing site. Optionally, the lancing device is tipped at an oblique angle relative to the skin surface, such that one of the first and second side edges 22a, 22b of the contact face 20 is pressed against the skin as the lancing device is drawn along the skin surface toward the lancing site. Drawing the contact face along the skin surface directs subcutaneous blood toward the lancing site. As the contact face is moved into position over the intended lancing site, the contact face is placed flat against the skin and the lancing device is triggered to lance the skin at the sampling site. After lancing, the user optionally can again draw the contact face along the skin toward the lancing site one or more times to direct more blood toward the lancing site and assist in expressing a sufficient sample size from the wound at the lancing site.

[00018] While the invention has been described with reference to preferred and example embodiments, it will be understood by those skilled in the art that a variety of modifications, additions and deletions are within the scope of the invention, as defined by the following claims.

What is claimed is:

1. An endcap for a lancing device, the endcap having a first end for connection to the lancing device and a second end comprising a contact face surrounding an opening for passing at least the sharp tip portion of a lancet, the contact face having a length substantially greater than its width and having at least one side edge along its length.
2. The endcap of Claim 1, comprising first and second side edges along its length on opposite sides of the contact face.
3. The endcap of Claim 2, further comprising curved ends of the contact face extending between said first and second side edges.
4. The endcap of Claim 3, further comprising outwardly flared first and second sides between the first and second ends of the endcap.
5. The endcap of Claim 4, wherein each outwardly flared side comprises one or more gripping surfaces.
6. The endcap of Claim 1, wherein the contact face is substantially planar.
7. The endcap of Claim 1, wherein the length of the contact face is at least about three-quarters of an inch.
8. The endcap of Claim 1, wherein the length of the contact face is at least about one inch.
9. An endcap for a lancing device, the endcap having a first end for connection to the lancing device and a second end comprising a substantially planar contact face surrounding an opening for passing at least the sharp tip portion of a lancet, the contact face having a length substantially greater than its width and having at least one straight side edge along its length, the endcap further comprising outwardly flared first and second sides between its first and second ends, each outwardly flared side comprising a gripping surface.

10. A lancing device for collecting a sample of body fluid from a sampling site on the skin of a subject, said lancing device comprising a lancet and a housing comprising an endcap, the lancet being movable between a first position within the housing and a second position wherein at least a sharp tip portion of the lancet extends through an opening in the endcap, and wherein the endcap comprises a substantially planar contact face surrounding the opening, the contact face having a length substantially greater than its width and having at least one straight side edge along its length.
11. The lancing device of Claim 10, comprising first and second straight side edges along its length on opposite sides of the contact face.
12. The lancing device of Claim 11, further comprising curved ends of the contact face extending between said first and second side edges.
13. The lancing device of Claim 10, further comprising outwardly flared first and second sides between first and second ends of the endcap.
14. The lancing device of Claim 13, wherein each outwardly flared side comprises a gripping surface.
15. The lancing device of Claim 10, wherein the length of the contact face is at least about three-quarters of an inch.
16. The lancing device of Claim 10, wherein the length of the contact face is at least about one inch.

17. A method of lancing skin to collect a fluid sample, the method comprising:
 - placing a contact face of a lancing device against a subject's skin a distance away from a lancing site;
 - drawing the contact face along the skin toward the lancing site; and
 - lancing the skin at the lancing site.
18. The method of Claim 17, further comprising again drawing the contact face along the skin toward the lancing site after lancing the skin.
19. ~~The method of Claim 17, further comprising tipping the lancing device at an angle to~~ bring an edge of the contact face into contact with the skin, and drawing the edge of the contact face along the skin toward the lancing site.

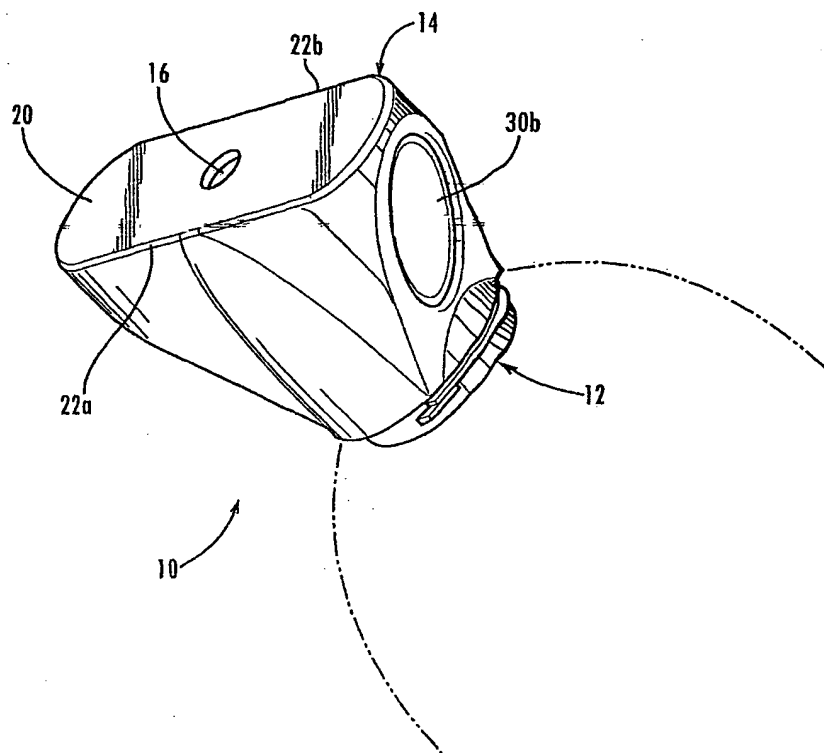


Fig. 1